

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problems Mailbox.**

SURGICAL CLIP

Patent number: GB2251794
Publication date: 1992-07-22
Inventor: BLUNDEN JOSEPH ALBERT;
CASEY DONN
Applicant: CASEY DONN (GB); CASEY
MEDICAL PROD (GB)

Also published as:

WO9212675 (A1)
WO9212675 (A1)

Classification:

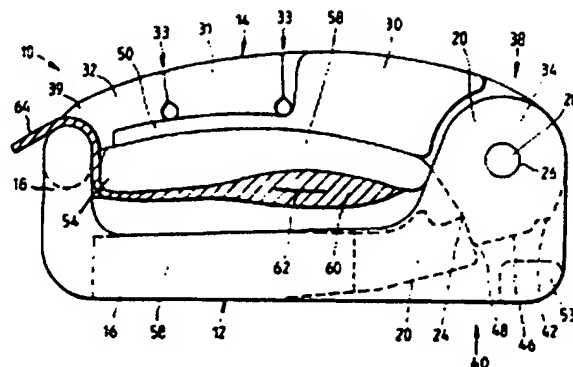
- international: A61F6/20
- european: A61B17/122

Application number: GB19910000967 19910116

Priority number(s): GB19910000967 19910116

Abstract of GB2251794

A plastics clip (10) for performing sexual sterilization comprises two jaws (12, 14), each having a lining of silicone rubber, hinged to move from an open position to the closed position shown, in which a Fallopian tube (60) is occluded. A catch mechanism (40) biases the jaws (12, 14) apart when the clip is open, by means of pressure from a resilient finger (22) on a cam profile (46) attached to the upper jaw (14). The finger (22) and underside of the cam profile (46) engage when the jaws reach their closed position, and lock the jaws closed. The upper jaw (14) has hinges (33) along its shank with the free end portion (32, 31) of the shank being biased towards and pivotable away from the lower jaw (12). A thick portion (54) of the resilient lining (58) at the free end



of the upper jaw impinges on the mesosalpinx (64) as the jaws are pivoted together, preventing escape of the tube before the clip is closed. The hinges (33) are configured such that the upper jaw (14) becomes straight and rigid when the jaws reach their closed position.

Data supplied from the **esp@cenet** database - Worldwide

(12) UK Patent Application (19) GB (11) 2 251 794 A

(43) Date of A publication 22.07.1992

(21) Application No 9100967.0

(22) Date of filing 16.01.1991

(71) Applicant
Casey Medical Products Limited

(Incorporated in the United Kingdom)

141 Newmarket Road, Cambridge, CB5 8HA,
United Kingdom

(72) Inventors
Donn Casey
Joseph Albert Blunden

(74) Agent and/or Address for Service
Reddie & Grose
16 Theobalds Road, London, WC1X 8PL,
United Kingdom

(51) INT CL⁶
A61F 6/20 // A61B 17/12

(52) UK CL (Edition K)
A5R REL
E2A AGKD A370 A375 A376 A378
U1S S1027 S1048

(56) Documents cited
GB 2212201 A GB 2190297 A EP 0246087 A
EP 0178469 A US 4726372 A

(58) Field of search
UK CL (Edition K) A5R REL RES, E2A AGKD AGKF
AGW
INT CL⁶ A61B, A61F, F16B

(64) Surgical clip

(57) A plastics clip 10 for occlusion of a fallopian tube 60 comprises two jaws 12, 14 lined with silicone rubber, the upper jaw 14 having hinges 33 along its shank with the end portion 32, 31 being biased towards and pivotable away from the lower jaw. The hinges 33 are configured such that the upper jaw 14 becomes straight and rigid when the jaws are closed. A catch mechanism 40 biases the jaws apart when the clip is open, by means of pressure from a resilient finger 22 on a cam profile 46 attached to the upper jaw, the finger and underside of the cam profile engaging when the jaws reach their closed position to lock the jaws closed. In an alternative embodiment the hinge means is a pivot pin 37 which passes through extensions of the shank portions, a projection 43 of disc-like extension 36 on the first portion 30 encountering a stop 44 on the second portion 31 when the upper jaw is straight.

Fig.3

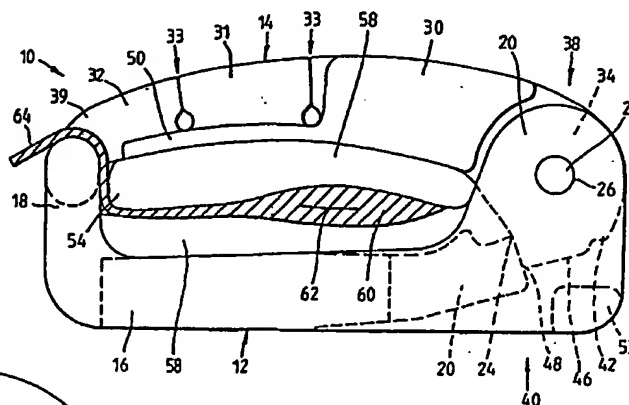
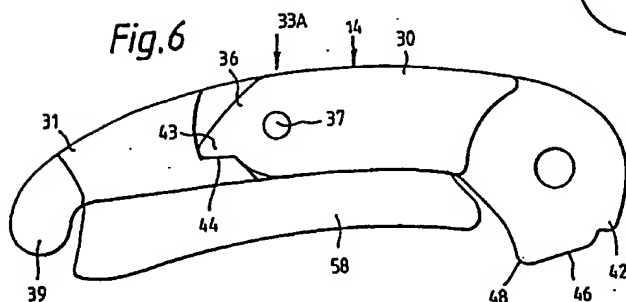


Fig.6



At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.
The print reflects an assignment of the application under the provisions of Section 30 of the Patents Act 1977.

GB 2 251 794 A

Fig.1

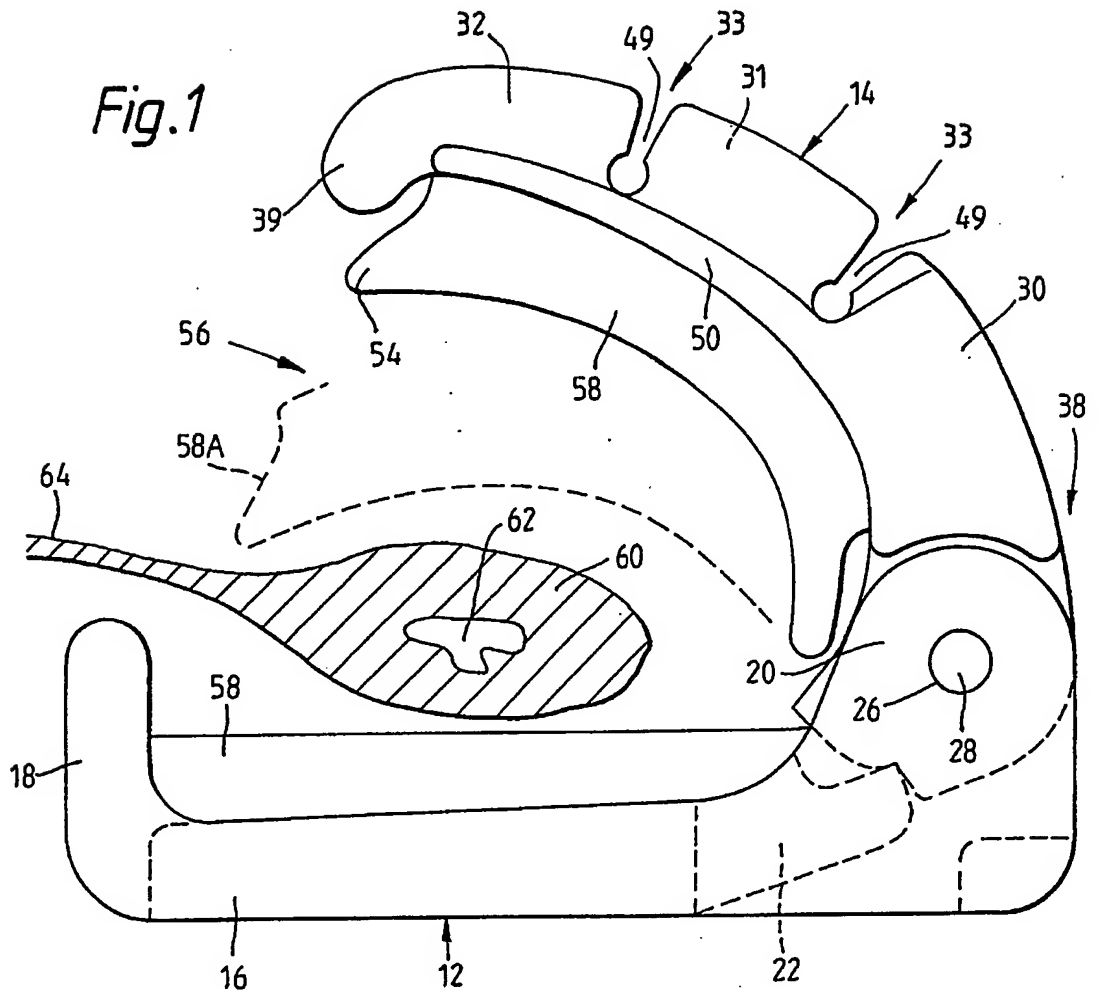


Fig.2

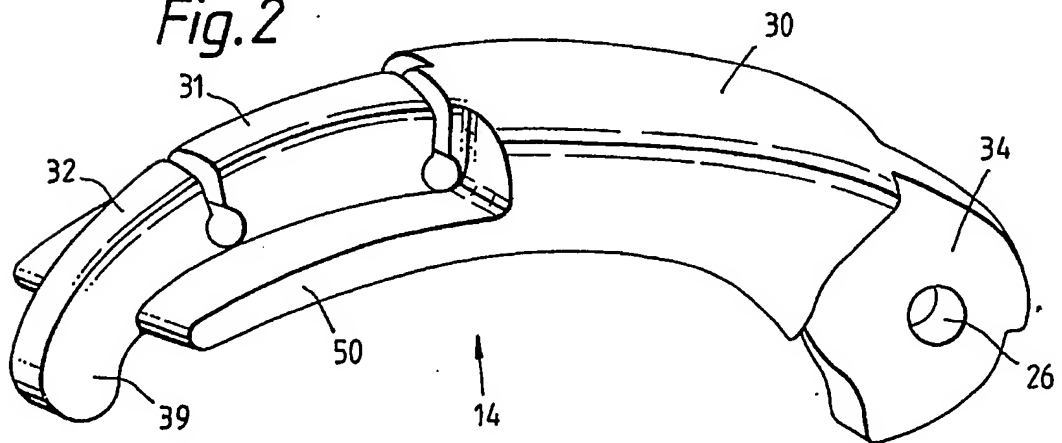


Fig.3

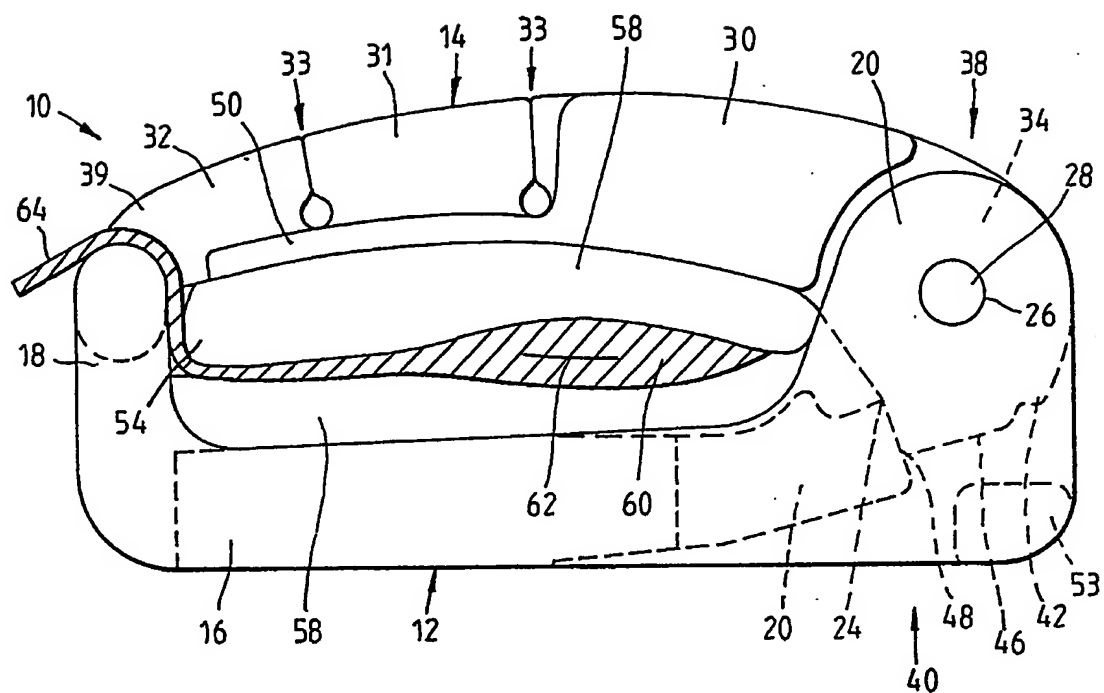


Fig.4

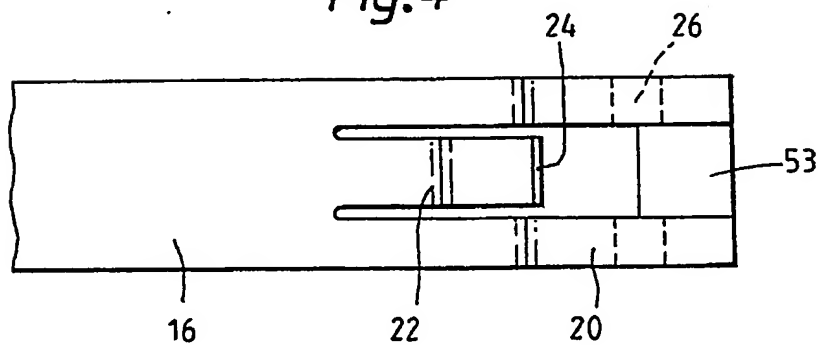


Fig.5

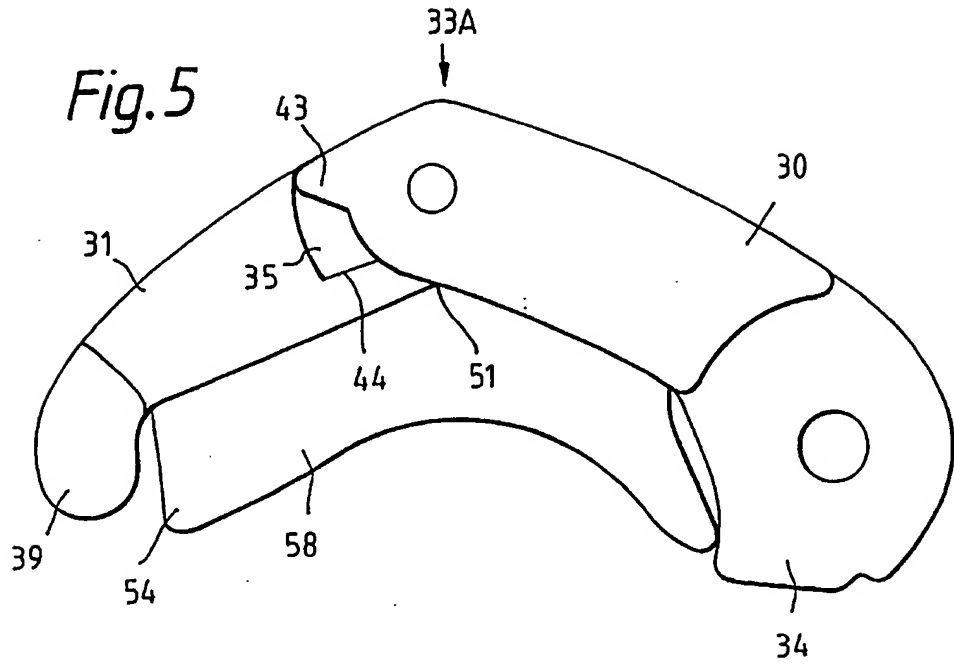


Fig.6

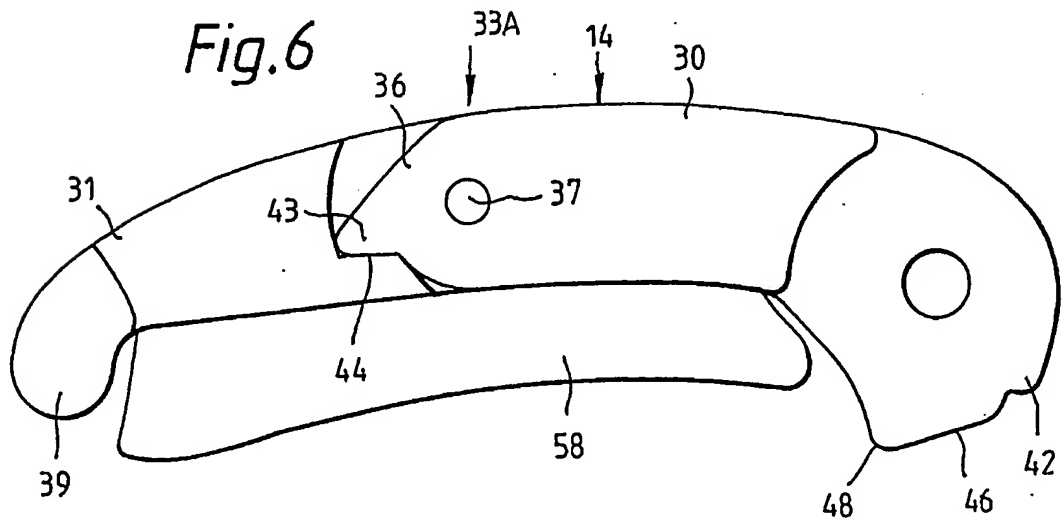


Fig.7

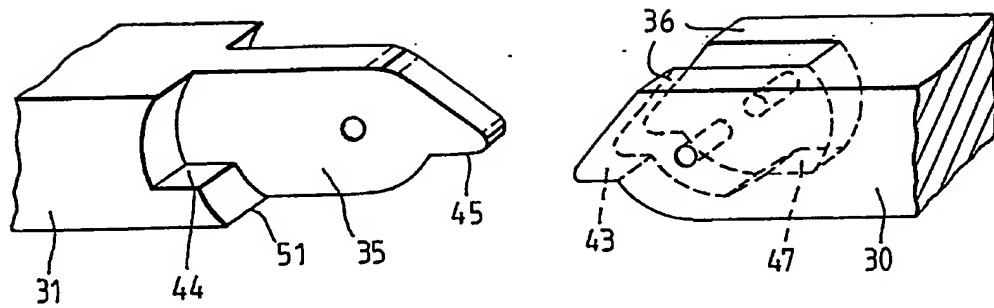
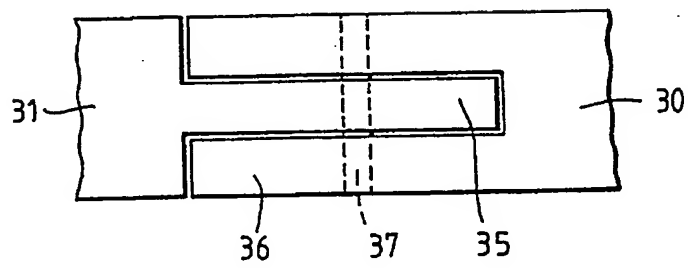


Fig.8



SURGICAL CLIP

The present invention relates to surgical clips for occluding bodily ducts, and, in particular, to clips for performing sexual sterilization, especially in females. Such clips comprise two jaws of rigid material hinged together to form a mouth for receiving a bodily duct to be occluded by closing the jaws.

A problem which occurs with such clips is that, during closure, the bodily duct is squeezed out of the mouth before closure is complete. Various methods have been tried for preventing this, including a hook portion at the free end of at least one of the jaws and teeth on the inner face of each jaw.

In accordance with the present invention there is provided a surgical clip for performing sexual sterilization, the clip having two jaws hinged together to form a mouth for receiving a bodily duct to be occluded by closing the jaws, in which one of the jaws comprises at least two jaw parts joined by hinge means, the hinge means allowing the jaw parts to pivot relative to each other. The hinged upper jaw acts to capture the bodily duct before the clip is closed.

When the jaws are open the hinged jaw is in an angled position with the jaw part or parts, forming the free end thereof pivoted about the hinge means, towards the other jaw. Biasing means may be provided to urge the free end jaw part or parts to such a position and a stop or stops may be provided to limit the extent of pivotal movement towards the other jaw. As the jaws close, the free end of the hinged jaw impinges on the other jaw; the angled hinged jaw and the other

jaw form an opening within which the duct is trapped. Further closing of the jaws will cause the hinged jaw to compress and thereby occlude the duct, at the same time straightening out the hinged jaw. A further stop or stops may be provided to limit the extent of pivotal movement of the free end jaw part or parts of the hinged jaw away from the other jaw. The stop or stops may limit the pivotal movement at the point where the jaw members extend, from the hinge means therebetween, in substantially opposite directions, the is to say when the jaw is straight. A catch mechanism may be provided to hold the jaws in position when the mouth is closed.

The biasing means may comprise a length of resiliently elastic material under tension and attached to the hinged jaw on either side of the hinge means. Such material would hold the free end part or parts of the hinged jaw angled towards the other jaw when the jaws were in the open position and stretch to allow the hinged jaw to straighten as the clip is closed.

The resiliently elastic material may be used to provide a resilient lining to the jaws of the clip.

The hinged jaw may be a unitary moulding and the hinge means may comprise a portion of the jaw of reduced thickness. Alternatively, the hinge means may be a hinged joint with a pivot pin about the axis of which the adjacent jaw parts pivot relative to each other.

Embodiments of a clip according to the invention will now be described in detail, by way of example, with reference to the accompanying drawings in which:

Fig. 1 is an elevational view of a clip according to a first embodiment of the present invention in an open position;

Fig. 2 is a perspective view of a part of the clip of Figure 1 with the lower jaw and resilient lining removed;

Fig. 3 is an elevational view of the clip of Figure 1 with its jaws closed around a Fallopian tube;

Fig. 4 is a plan view of a part of the clip of Figure 1 with the upper jaw and resilient lining removed;

Fig. 5 is an elevational view of the upper jaw of a clip according to a second embodiment of the present invention, in an angled position;

Fig. 6 shows the jaw of Figure 5 in a straight position;

Fig. 7 is a perspective view of part of the jaw of Figure 5 with the jaw members separated; and

Fig. 8 is a plan view of the jaw part of Figure 7 with the jaw members joined.

Figs. 1 to 3 show a first embodiment of a surgical clip 10 for performing sexual sterilization, comprising upper and lower jaws 14,12 connected at one end by a hinge 38 and movable between an open position (Fig.1), in which a Fallopian tube 60 may be introduced between the jaws, and a closed position (Fig.3) in which the tube is trapped between the jaws and occluded by them.

The lower jaw 12 comprises a rigid shank 16 having two generally tooth-like perpendicular extensions 18 at one end, and at the other end two generally disc-like extensions 20. A resilient finger 22 extends from the shank 16, generally in the direction of the shank, to lie between the two disc-like extensions 20, as shown in Figure 4. A transverse bridging piece 53 joins and strengthens the two extensions. The centres of the disc-like extensions 20 are aligned and have holes 26 formed in them which receive a pivot pin 28. The resilient finger 22 forms part of a catch and bias mechanism 40 to be described.

The upper jaw 14 comprises first, second and third rigid jaw parts or shank portions 30,31,32 joined by respective hinged joints 33. At one end of the upper jaw 14 is a single disc-like extension 34 provided with a hole 26 for receiving the pivot pin 28. In the assembled clip 10, the disc 34 lies between the discs 20 with pivot pin 28 located in the holes 26 to allow the disc 34 to rotate relative to the discs 20 while restricting lateral movement.

At the other end of the upper jaw 14 (the free end of the jaw) there is a tooth portion 39 which, when the clip is closed, lies between the two teeth 18 on the lower jaw 12.

The hinged joints 33 are provided with keyhole slots 49 extending transversely across the upper jaw 14, the slots 49 being open on that side of the upper jaw away from the lower jaw 12. Below the keyhole slots 49, joining the shank portions 30,31,32, is a reduced thickness portion 50 of the jaw. This reduced thickness portion 50, in combination with the keyhole slots 49, permits the second and third shank portions 31, 32 to bend, relative to the first and second shank portions 30,31 respectively towards and away from the lower jaw 12. As shown in Figure 2, the first shank portion 30 and reduced thickness portion 50 are of substantially the same width whilst the second and third shank portions 31,32 are narrower, being of substantially the same width as the tooth portion 39. Each jaw has a resilient lining 58 of, for example, silicone rubber moulded upon it. The depth of the lining 58 is increased towards the free end of the upper jaw 14 to provide a thick portion 54 of resilient material at the free end of the upper jaw.

The circumferential surface of the disc 34 forms part of the catch and bias mechanism 40. The surface forms a cam

profile having two discontinuities or steps separated by an inclined ramp. The inclined ramp 46 is a substantially straight surface, such that the radial distance of the surface from the pivot pin 28 increases smoothly. At its outermost end, the ramp surface 46 terminates in an inwardly extending radial step or lip 48. At its innermost end, the ramp surface 46 is bordered by an outwardly projecting stop surface 42.

With the clip 10 in the open position (Fig.1), the free end 24 of the resilient finger abuts the stop surface 42 which limits opening of the clip 10.

As the clip is being closed (shown by dotted line 58A in Fig. 1), the free end 24 of the finger 22 runs along the ramp surface 46 of the cam profile so that the finger 22 is gradually forced downwards as the clip closes. The ramp surface 46 is shaped so that the line of force from the point of contact of the finger 22 on the ramp surface 46 is offset from the pivot pin 28 (to the left of the pivot pin as shown in Fig. 1) at all times during closing of the clip. Consequently, during closing the clip 10 is strongly biased towards the open position. Prior to the free end 24 of the finger reaching the step 48 of the cam profile, any release of closing pressure will thus cause the clip to spring back to the fully open position (Fig. 1). The cam profile 46 is also contoured to provide increasing opening bias as the point of full closure is approached by deflecting the finger 22 further from the pivot 28 as it approaches the step 48.

Any further closing movement causes the free end 24 of the finger 22 to move past the step 48. Contact between the free end 24 of the finger and the ramp surface 46 ceases as the finger 22 reverts to its natural shape, moving towards the radial surface of the disc 34. The jaws 12,14 are thus locked

in the closed position (Fig.3) as the finger 22 cannot rise over the step 48 if attempts are made to open the clip 10.

The finger and cam catch and bias mechanism described above may be lubricated by a small drop of medical grade silicone oil.

The application of a clip 10 to occlude a single Fallopian tube will now be described with particular reference to Figs. 1 and 3.

With the clip in the fully open position (Fig.1) the Fallopian tube 60 and an area of the mesosalpinx 64 are placed in the mouth 56 formed between jaws 12,14. The tube 60 then occupies a plane generally perpendicular to the plane of the jaws 12,14. The tube 60 is free to move in and out of the mouth 56 although the thick portion 54 of the lining and the teeth 18 on the lower jaw 12 partially restrict the mouth 56.

In use, the jaws 12,14 hinge together to close the mouth 56 and trap the tube 60. At an intermediate position, the thick lining portion 54 has approached and just reached the mesosalpinx 64, holding it against the resilient lining 58 on the jaw 12, thus preventing the tube 60 escaping as further pressure is applied to close the clip. As the closure continues, the second and third portions 31, 32 of the upper jaws start to pivot about the respective hinged joints 33. The resilience of the reduced thickness portion 50 opposes this movement and keeps the thick lining portion 54 in contact with the mesosalpinx 64. The contact between the thick lining portion 54 and mesosalpinx 64, and the mating of the tooth portion 39 with the recess between the teeth 18 restricts the movement of the tube 60 relative to the clip.

As the point of full closure is approached, the upper jaw 14 straightens with the keyhole slots 49 closing. At the point of full closure, the keyhole slots 49 are closed and the end faces of the third and first shank portions 30,32 impinge on respective end faces of the second shank portion 31 thereby making the upper jaw 14 rigid and straight when the clip 10 is closed.

When the point of full closure has been reached (Fig.3) and the jaws 12,14 are locked in the closed position by the catch mechanism 40, the lumen 62 is fully occluded. The resilient linings 58 exert a compressive force on the tube 60, which serves to prevent recanalisation when necrosis of the muscular tissue of the tube 60 occurs.

The tooth portion 39 is much narrower than the recess between the teeth 18 with which it mates when the clip 10 is closed. This allows the vulnerable mesosalpinx 64, to which the Fallopian tube 60 is attached, to pass undamaged through the closed mouth of the clip, whilst preventing escape of the Fallopian tube.

The clip 10 is particularly suited for use with a laparoscope or similar application methods since, because of the opening bias of the jaws, it will automatically re-open to its fullest extent after passing through a laparoscopic cannula tube. In use, the clip 10 will spring fully open if not completely closed, thereby providing the surgeon with a clear-cut end point to the operation. Additionally, the opening bias assists in firmly locating the clip in the mouth of an applicator.

A second embodiment of hinged jaw 14 will now be described with reference to Figures 5 to 8. The jaw has first

and second shank portions 30, 31 with a hinged joint 33A therebetween. The hinged joint 33A is shown in greater detail in Figures 7 and 8. At the joint, the second shank portion 31 has a generally disc-like extension 35 which lies between two generally disc-like extensions 36 on the first shank portion 30. A pivot pin 37 passes through the discs 35,36 allowing the second shank portion 31 to pivot relative to the first shank portion 30. A projection 43 from the circumferential surface of each disc 36 on the first shank portion 30 encounters a stop 44 formed on the second shank portion when the two shank portions 30,31 extend, from the hinged joint, in substantially opposite directions, that is to say when the upper jaw 14 is straight.

Similarly, projection 45 from the circumferential surface of the disc 35 on the second shank portion 31 encounters a stop 47 formed on the first shank portion 30 to limit the pivotal movement of the second shank portion 31 away from the other jaw 12. Further stops 51, provided by extensions of each stop 44 on the second shank portion 31, impinge on the underside of the first shank portion 30 (as shown in Fig.5) to limit the pivotal movement of the second shank portion towards the other jaw 12. The further stop 51 limits such movement to about 45° from the straight jaw position.

The circumferential surfaces of the discs 35,36 are so shaped that, whether the jointed jaw 14 is straight (as in Fig. 6) or angled (as in Fig.5), there are no sharp corners or edges projecting from the hinged joint 33A.

The pivot pin 37 in the hinged joint 33A is preferably of titanium although certain plastics materials may be used.

As with the first embodiment, each jaw has a resilient lining 58 of, for example, silicone rubber moulded upon it.

On the upper jaw 14, the lining 58 is moulded in position with the second shank portion 31 at an angle to the first. The lining 58 on the upper jaw 14 acts to bias the jaw portions to an angled position. Straightening of the jaw puts the lining 58 in tension and, in the absence of a counteracting force, the second shank portion 31 will be pulled towards the lower jaw 12 about the pivot pin 37 as the lining contracts.

The embodiments of the clip described are intended to be manufactured from mouldable materials such as polycarbonate plastics materials which lend themselves to mass production methods whilst at the same time allowing manufacture of clips having smooth surfaces and rounded edges such as to be largely atraumatic in use. Materials for the jaws, linings and pivot pins are available which satisfy all surgical requirements as to their toxicity and purity whilst still being suitable for such production methods.

CLAIMS

1. A surgical clip for performing sexual sterilization, the clip having two jaws hinged together to form a mouth for receiving a bodily duct to be occluded by closing the jaws, in which one of the jaws comprises at least two jaw parts joined by hinge means, the hinge means allowing the jaw parts to pivot relative to each other.
2. A clip according to claim 1 in which the hinged jaw has a stop to limit the extent of pivotal movement of the jaw parts about the hinge means joining the said jaw parts, away from the other jaw.
3. A clip according to claim 2 in which the limit of pivotal movement occurs when the jaw parts extend, from the hinge means therebetween, in substantially opposite directions.
4. A clip according to any of claims 1 to 3 in which the hinged jaw has biasing means opposing movement of the jaw part forming the free end thereof away from the other jaw.
5. A clip according to claim 4 in which the biasing means includes a length of resiliently elastic material under tension and attached to the jaw parts on each side of the or each hinge means.
6. A clip according to claim 4 in which the biasing means includes a strip of resilient material moulded on the hinged jaw on the side which bears on the bodily duct, the material being moulded onto the jaw when the jaw part forming the free end thereof is pivoted about the hinge means towards the other jaw.

7. A clip according to any preceding claim, in which the hinge means is a hinged joint with a pivot pin about the axis of which the adjacent jaw parts pivot relative to each other.

8. A clip according to claim 7 in which the hinged jaw has a stop to limit the extent of pivotal movement of the jaw parts, about the hinged joint therebetween, towards the other jaw.

9. A clip according to claim 8 in which the limit of pivotal movement occurs when the jaw parts have pivoted through about 45° from a position in which the jaw parts extend, from the hinged joint therebetween, in substantially opposite directions.

10. A clip according to any of claims 1 to 4 in which the hinged jaw is a unitary moulding of resilient material and the hinge means is a portion of the jaw of reduced thickness.

11. A clip according to claim 10 when appendant to claim 4, in which the said biasing means is provided by the resilience of the reduced thickness portion of the jaw.

12. A surgical clip for performing sexual sterilization, the clip being substantially as hereinbefore described with reference to figures 1 to 4 or 4 to 8 of the drawings.

- 12 -

Patents Act 1977
Examiner's report to the Comptroller under
Section 17 (The Search Report)

Application number 9100967.0

Relevant Technical fields

- (i) UK Cl (Edition K) A5R (REL RES)
E2A (AGKD AGKF AGW)
- (ii) Int Cl (Edition 5) A61B A61F F16B

Search Examiner

L V Thomas

Databases (see over)

(i) UK Patent Office

(ii)

Date of Search

1 March 1991

Documents considered relevant following a search in respect of claims

1-12

Category (see over)	Identity of document and relevant passages		Relevant to claim(s)
X	GB A 2212201	(CASEY) See lines 18-28 page 3, lines 2-15 page 5 and figures 2 and 3	1, 4-6, 10
X	GB A 2190297	(FEMCARE LTD) See lines 69-76 page 1, lines 1-4 page 2 and figures 1, 2, 6 and 7	1
X	EP A 0246087	(CASEY) See line 45 column 3 - line 21 column 4 and figures 1 and 6	1, 4-6, 10
X	EP A 0178469	(AMERICAN CYANAMID) See line 24 page 2 - line 20 page 3, line 25 page 9 - line 21 page 10 and figure 9	1, 10
X	US 4726372	(PERLIN) See lines 56-60 column 3 and figures 1 and 2	1, 4, 10 11

SF2(p)

H79ABB

Category	Identity of document and relevant passages	Relevant to claim(s)

Categories of documents

X: Document indicating lack of novelty or of inventive step.

Y: Document indicating lack of inventive step if combined with one or more other documents of the same category.

A: Document indicating technological background and/or state of the art.

P: Document published on or after the declared priority date but before the filing date of the present application.

E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.

&: Member of the same patent family, corresponding document.

Databases: The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).